IgG at CE

IgG

Turbidimetric method

REF 3165010
1 x 50 mL
CONTENTS
R1.Reagent 1 x 50 mL

For *in vitro* diagnostic use only

PRINCIPLE

IgG at is a quantitative turbidimetric assay[1,2] for the measurement of IgG in human serum or plasma.
Anti-human IgG antibodies form insoluble complexes when mixed with samples containing IgG. The scattering light of the immunocomplexes depends of the IgG concentration in the patient sample, and can be quantified by comparison from a calibrator of known IgG concentration.

REAGENTS COMPOSITION

R1 **IgG at**. Goat antibodies anti-human IgG, tris buffer 20 mmol/L, pH 8.2. Sodium azide 0.95 g/L.

Plasma Protein Multicalibrator. Protein Calibrator. Optional . Ref: 3910005.

Precautions: The reagent contains sodium azide 0.95 g/L. Avoid any contact with skin or mucous.

STORAGE AND STABILITY

1. Store at 2-8ºC.
   The reagent is stable until the expiry date stated on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Does not use the reagent after the expiry date.
2. Presence of particles, turbidity and/or the absorbance of blank reagent > 0.3 at 540 nm are sign of deterioration.

REAGENT PREPARATION

R1 Ready to use.

Calibration curve. Dilute the Plasma Protein Calibrator in NaCl 9 g/L as follow:

Dilution	1	2	3	4	5	6
Calibrator (µL)	--	10	25	50	75	100
NaCl 9 g/L (µL)	100	90	75	50	25	--
Factor	0	0.1	0.25	0.5	0.75	1.0

Multiply the concentration of the IgG Protein Calibrator by the corresponding factor to obtain the IgG concentration of each dilution.

SAMPLES

Fresh serum and EDTA or heparinized plasma.
IgG in serum or plasma is stable 7 days at 2-8ºC or 3 months at –20ºC.
Samples with presence of fibrin should be centrifuged before testing. Highly hemolyzed or lipemic samples are not suitable for testing.

INTERFERENCES

Bilirubin (40 mg/dL) and rheumatoid factors (300 UI/mL) do not interfere. Hemoglobin (8 g/L) and lipemia (10 g/L) may affect the results. Other substances may interfere[5].

MATERIAL REQUIRED

- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostatable at 37ºC capable to read at 540 ± 20 nm.
- Cuvettes with 1cm pathlength.
- Pipettes to measure reagent and samples.

PROCEDURE

1. Prewarm the reagent and the photometer (cuvette holder) to 37ºC.
2. Using distilled water zero the instrument at 540 nm.
3. Pipette into a cuvette:

Sample / Calibrator	7 µL
Reagent (R1)	1.0 mL

4. Mix well and insert the cuvette into the photometer. Record the absorbance (A) after 2 minutes of the sample or calibrator addition.

CALCULATION

Plot the different absorbance values (A) against the IgG concentration of each calibrator dilution. IgG concentration in the sample is calculated by interpolation of its (A) value in the calibration curve.

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REFERENCE VALUES

Adults[3]: 700 – 1600 mg/dL
Newborn[4]: 299 – 852 mg/dL
It is recommended that each laboratory establishes its own reference range.

QUALITY CONTROLS

To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

REF **3915010 PLASMA PROTEIN CONTROL N-I**
Normal level. Assayed.

REF **3915015 PLASMA PROTEIN CONTROL N-II**
Abnormal level. Assayed.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

CLINICAL SIGNIFICANCE

Quantification of immnunoglobulins in serum is important for the diagnosis of primary or secondary immunodeficiency, for monitoring of immnuglobulin therapy, and for following the clinical course of multiple myeloma[4].

IgG is the most important immunoglobulin produced by plasma cells, and represents about 75% of the total immunoglobulins[4].

Congenital and acquired immunodeficiency are the most important causes of IgG deficit[3,4].

Polyclonal hyperimmunoglobulinemia (normal response to infections), hepatitis, cirrhosis as well as autoimmune diseases are other causes that increase IgG concentration.

Increments of monoclonal IgG (paraproteins) are found in multiple myoloma, lymphocytic leukemia, and Waldenström macroglobulinemia[4].

ANALYTICAL PERFORMANCE

- ***Linearity limit.*** Up to 3000 mg/dL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 en ClNa 9 g/L and retested again.
- ***Detection limit.*** Values less than 3.0 mg/dL give non-reproducible results.
- ***Analytical sensitivity.*** Using this reagent and method an ΔA of 0.467 mA at 540 nm is equivalent to 1 mg/dL of IgG at a concentration of 1770 mg/dL.
- ***Prozone effect.*** Prozone effect is not observed up to 7000 mg/dL of IgG.
- ***Precision.***

mg/dL	Within-run		Between-run	
Mean	706	1404	706	1404
SD	26.0	64.3	35.8	89.3
CV%	3.7	5.1	4.6	6.4
N	10	10	10	10

Instrument: Cobas Mira

- ***Accuracy:*** Results obtained with this reagent did not show systematic differences when compared with commercial reagents of similar characteristics. Details of comparison are available on request.

NOTES

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.
2. The linearity limit depends on the sample/reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
3. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCES

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